



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO.               | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------|-------------|----------------------|---------------------|------------------|
| 09/926,661                    | 02/28/2002  | Masatoshi Chiba      | P21749              | 5687             |
| 7055                          | 7590        | 06/08/2006           | EXAMINER            |                  |
| GREENBLUM & BERNSTEIN, P.L.C. |             |                      | KOLKER, DANIEL E    |                  |
| 1950 ROLAND CLARKE PLACE      |             |                      | ART UNIT            |                  |
| RESTON, VA 20191              |             |                      | PAPER NUMBER        |                  |
|                               |             |                      | 1649                |                  |

DATE MAILED: 06/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

09/926,661

Applicant(s)

CHIBA, MASATOSHI

Examiner

Daniel Kolker

Art Unit

1649

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 16 May 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).


4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1, 3, 4 and 6-16.  
Claim(s) withdrawn from consideration: 22-28.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

  
SHARON TURNER, PH.D.  
PRIMARY EXAMINER  
6-2-06


to applicant to rebut the case and distinguish the product from the prior art. Applicant has done neither.

Claims 12 - 14 are drawn to compositions further comprising, in the most specific recitation, a polyoxyethylene ether surface active agent. Nakamura teaches that Polysobrate-80 is one of the agents which can be added to the composition (column 10 lines 4-5) and the specification clearly considers this to be a specific polyoxyethylene ether (see p. 9 final paragraph). Applicant is reminded that Nakamura teaches that Nakamura teaches that the agents listed in that paragraph can be used in combination.

Claim 15 requires that the lyophilized product be prepared in a vial or an ampoule. Again, this is a product-by-process limitation which does not distinguish the product from the prior art. While Nakamura is silent, in this paragraph, as to whether or not the product is made in a vial, the container does not change the product contained therein.

The rejection of claims 1 and 16 as either anticipated by, or in the alternative obvious over, Nakamura is maintained for the reasons of record. Applicant argues that the Nakamura reference does not motivate inclusion of arginine. Applicant's arguments have been fully considered but they are not persuasive. Rejections under §§ 102/103 are appropriate when the prior art reference appears to disclose the claimed invention except that it is silent as to an inherent property. MPEP 2112(III). Here, the reference is silent as to whether or not the amount of arginine included is sufficient to prevent HGF aggregate formation.

Claims 1, 3-4, and 6 - 16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura and Tanaka. This rejection is maintained for the reasons of record. Applicant argues, on p. 14 of the remarks, that nothing in Nakamura points the artisan of ordinary skill to change the pH. However, as explained in detail previously, Tanaka teaches that changing the pH is advantageous, as it allows for more rapid dissolution. In fact, this is one of the factors that Nakamura suggests optimizing (see Nakamura, column 9 lines 52 - 55). Thus the rejection stands for the reasons of record.

  
SHARON TURNER, PH.D.  
PRIMARY EXAMINER  
6-2-06